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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,768	10/29/2001	Eric H. Baehrecke	4115-131	3246

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INTELLECTUAL PROPERTY / TECHNOLOGY LAW
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EXAMINER
DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
1642	9

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/016,768	BAEHRECKE, ERIC H.	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-25* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's election of group 2, claims 1-5, SEQ ID NO:2 in paper No: 8 is acknowledged.

Applicant adds new claims 20-25.

After review and reconsideration, the restriction requirement of paper No;7 is withdrawn and is replaced with the following new restriction requirement.

Claim 25 could not be considered, because claim 25 is drawn to a polynucleotide comprising an amino acid sequence of SEQ ID NO:2, and because a polynucleotide cannot be a polypeptide. Claim 25 will be considered and assigned to proper group upon amendment of claim 25.

Further, although the listing of the claims recites claims 9-12, 14-17, 19 as cancelled, however there is no recitation in the response that requests to cancel these claims.

Accordingly, the following restriction applies to claims 1-24.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Groups 1-6. Claims 1-5, 20, 22, drawn to a polypeptide that modulates programmed cell death, comprising SEQ ID NO:1, 2, 3, 4, 5 or 8, or variants thereof, classified in class 530, subclass 350. Each polypeptide constitutes a single invention.

Groups 7-12. Claims 6-8, 18, drawn to a method for treating a disorder which is Alzheimer's disease, comprising administering a polypeptide that modulates

programmed cell death, comprising SEQ ID NO:1, 2, 3, 4, 5 or 8, classified in class 514, subclass 2. A method using each polypeptide constitutes a single invention.

Groups 13-18. Claims 6-8, 18, drawn to a method for preventing a disorder which is Alzheimer's disease, comprising administering a polypeptide that modulates programmed cell death, comprising SEQ ID NO:1, 2, 3, 4, 5 or 8, classified in class 514, subclass 2. A method using each polypeptide constitutes a single invention.

Groups 19-24. Claims 6-8, 18, drawn to a method for treating a disorder which is cancer, comprising administering a polypeptide that modulates programmed cell death, comprising SEQ ID NO:1, 2, 3, 4, 5 or 8, classified in class 514, subclass 2. A method using each polypeptide constitutes a single invention.

Groups 25-30. Claims 6-8, 18, drawn to a method for preventing a disorder which is cancer, comprising administering a polypeptide that modulates programmed cell death, comprising SEQ ID NO:1, 2, 3, 4, 5 or 8, classified in class 514, subclass 2. A method using each polypeptide constitutes a single invention.

Groups 31-36. Claims 6-8, 18, drawn to a method for treating a disorder which is Parkinson's disease, comprising administering a polypeptide that modulates programmed cell death, comprising SEQ ID NO:1, 2, 3, 4, 5 or 8, classified in class 514, subclass 2. A method using each polypeptide constitutes a single invention.

Groups 37-42. Claims 6-8, 18, drawn to a method for preventing a disorder which is Parkinson's disease, comprising administering a polypeptide that modulates programmed cell death, comprising SEQ ID NO:1, 2, 3, 4, 5 or 8, classified in class 514, subclass 2. A method using each polypeptide constitutes a single invention.

Groups 43-48. Claims 6-8, 18, drawn to a method for treating a disorder which is rheumatoid arthritis, comprising administering a polypeptide that modulates programmed cell death, comprising SEQ ID NO:1, 2, 3, 4, 5 or 8, classified in class 514, subclass 2. A method using each polypeptide constitutes a single invention.

Groups 49-55. Claims 6-8, 18, drawn to a method for preventing a disorder which is rheumatoid arthritis, comprising administering a polypeptide that modulates programmed cell death, comprising SEQ ID NO:1, 2, 3, 4, 5 or 8, classified in class 514, subclass 2. A method using each polypeptide constitutes a single invention.

Groups 56-61. Claims 6-8, 18, drawn to a method for treating a disorder which is chronic or acute inflammation, comprising administering a polypeptide that modulates programmed cell death, comprising SEQ ID NO:1, 2, 3, 4, 5 or 8, classified in class 514, subclass 2. A method using each polypeptide constitutes a single invention.

Groups 62-67. Claims 6-8, 18, drawn to a method for preventing a disorder which is chronic or acute inflammation, comprising administering a polypeptide that modulates programmed cell death, comprising SEQ ID NO:1, 2, 3, 4, 5 or 8, classified in class 514, subclass 2. A method using each polypeptide constitutes a single invention.

Groups 68-73. Claims 6-8, 18, drawn to a method for treating a disorder which is AIDs, comprising administering a polypeptide that modulates programmed cell death, comprising SEQ ID NO:1, 2, 3, 4, 5 or 8, classified in class 514, subclass 2. A method using each polypeptide constitutes a single invention.

Groups 74-79. Claims 6-8, 18, drawn to a method for preventing a disorder which is AIDs, comprising administering a polypeptide that modulates programmed cell

death, comprising SEQ ID NO:1, 2, 3, 4, 5 or 8, classified in class 514, subclass 2. A method using each polypeptide constitutes a single invention.

Groups 80-85. Claims 6-8, 18, drawn to a method for treating a disorder which is degenerative liver disease, comprising administering a polypeptide that modulates programmed cell death, comprising SEQ ID NO:1, 2, 3, 4, 5 or 8, classified in class 514, subclass 2. A method using each polypeptide constitutes a single invention.

Groups 86-91. Claims 6-8, 18, drawn to a method for preventing a disorder which is degenerative liver disease, comprising administering a polypeptide that modulates programmed cell death, comprising SEQ ID NO:1, 2, 3, 4, 5 or 8, classified in class 514, subclass 2. A method using each polypeptide constitutes a single invention.

Groups 92-98. Claims 9-11, 14-16, 19, drawn to a polynucleotide encoding a polypeptide that modulates programmed cell death, comprising SEQ ID NO: 1, 2, 3, 4, 5, 8 or 10, classified in class 536, subclass 23.1. Each polynucleotide constitutes a single invention.

Groups 99-104. Claim 12, drawn to a method for detecting a polynucleotide encoding SEQ ID NO: 1, 2, 3, 4, 5, or 8, classified in class 435, subclass 6. A method using each polynucleotide constitutes a single invention.

Groups 105-110. Claims 13, 24, drawn to a method for screening apoptosis inhibiting compounds, comprising contacting the test compound with a cell which expresses the protein of SEQ ID NO: 1, 2, 3, 4, 5, or 8, classified in class 435, subclass 7.1. A method using each protein constitutes a single invention.

Groups 111-116. Claim 17, drawn to an antibody that binds to the polypeptide of SEQ ID NO:1, 2, 3, 4, 5 or 8, classified in class 530, subclass 387.1. An antibody which binds to each polypeptide constitutes a single invention.

Group 117. Claim 21, drawn to a method for modifying the apoptotic activity of a cell, comprising contacting the cell with the polypeptide of SEQ ID NO:2 or variants thereof, classified in class 514, subclass 2.

Group 118. Claim 23, drawn to a method for generating an antibody to the polypeptide of SEQ ID NO:2, or variants thereof, classified in class 435, subclass 7.1.

In addition, upon election of any of groups 1-98, further election of the following patentably distinct species is required:

A polypeptide that increases or a polypeptide that decreases programmed cell death.

Upon election of any of groups 56-67, further election of the following patentably distinct species is required:

Chronic or acute inflammation.

The inventions are distinct, each from each other because of the following reasons:

Inventions (1-6, 92-98, 111-116) and (7-91, 99-110, 117-118) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05 (h). In this instant case, a polypeptide could be used for several purposes, e.g. for biochemical

assay, for making antibodies, and for making an affinity column to purify its antibodies; a DNA sequence could be used for the detection of similar DNA or RNA sequences, for making an expression vector, and for producing its encoded protein; and an antibody could be used for immunoassay, for purification of its antigen, and for detection of diseases.

The products of groups 1-6, 92-98, 111-116 are patentably distinct, because they are drawn to entirely different biochemicals , having different structures.

The methods of groups 7-91, 99-110, 117-118 are distinct from each other because they differ at least in objectives, method steps, reagents and/or dosages, and/or schedules used, response variables and criteria for success.

The species a polypeptide that increases or a polypeptide that decreases programmed cell death are distinct, because they have opposite properties.

The species chronic or acute inflammation are distinct, because they have different characteristics.

Because these inventions are distinct for the reason given above and have acquired a separate status in the art, and further, because the searches for the groups are not co-extensive, and therefore, it would be a serious burden for the Examiner to examine all the groups and species together, restriction for examination purposes as indicated is proper.

Applicants are required under 35 USC 121 to elect a single disclosed group for prosecution on the merits to which the claims shall be restricted. Applicant is further advised that if Applicant elects a group having species requirement, a response to this

requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendement of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

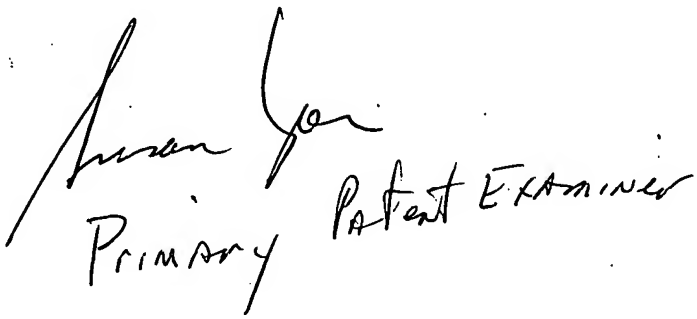
Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

MINH TAM DAVIS

February 06/2003



SUSAN UNGAR, PH.D
PRIMARY EXAMINER